

REMARKS

Claims 50-69 are pending in this application. The title is amended herein to more specifically define the claimed invention and the specification is amended herein to add a section describing the drawings and to correct some inadvertent typographical errors, as suggested by the Examiner. New claims 70-75 are added herein. Support for these new claims is found throughout the specification, as set forth below. No new matter is added by these amendments or new claims. In light of these amendments and new claims and the following remarks, applicants respectfully request entry of these amendments and new claims, reconsideration of this application and allowance of the pending claims to issue.

I. Oath or declaration defective

The Office Action states that the Declaration is defective because the city of residence of co-inventors Ramaswamy and Rajagopalan is omitted from the Declaration filed August 5, 2002 and that a new Declaration is required.

A substitute Declaration, providing the city of residence of all the co-inventors, is filed herewith, thereby mooted this objection and applicants respectfully request its withdrawal.

II. Priority claim

The Office Action states that applicants have not complied with the conditions for receiving the benefit of an earlier filing under 35 U.S.C. § 120. The Office Action further states that an application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet and that the specific reference to any prior nonprovisional application must include the relationship between the applications except when the reference is to a prior application of a CPA assigned the same application number. The Office Action also states that



after an acceptable claim for priority is submitted, the Examiner will forward the Request for Corrected Filing Receipt filed December 17, 2002 for action.

The specification is amended herein to contain a specific reference to the prior applications from which priority is claimed as well as the relationship between these applications. Applicants also request that the previously submitted Request for Corrected Filing Receipt not be forwarded for processing, as applicants will provide an alternate Request for Corrected Filing Receipt for this application.

III. Objection to disclosure

The Office Action states that the disclosure is objected to for various informalities recited below.

A. The disclosure is objected to because there is no Brief Description of the Drawings as required under 37 C.F.R. § 1.74.

The specification is amended herein at page 15, line 10 to include a section entitled "Brief Description of the Drawings." Therefore, this objection has been overcome and applicants respectfully request its withdrawal.

B. The disclosure is objected to because amphiphilicity is misspelled on page 8, line 3.

The specification is amended on page 8, line 3 to correct this misspelled word. Therefore, this objection has been overcome and applicants respectfully request its withdrawal.

C. The disclosure is objected to because patient is misspelled on page 22, line 11.

A handwritten signature or mark, possibly a stylized 'B' or a similar symbol, located in the bottom right corner of the page.

The specification is amended on page 22, line 11 to correct this misspelled word. Therefore, this objection has been overcome and applicants respectfully request its withdrawal.

D. The disclosure is objected to because the status of the U.S. patent application cited on page 40, line 29 should be updated.

The specification is amended on page 40, line 29 to update the status of this U.S. patent application. Additional amendments have been made in this paragraph to correct typographical errors in some of the citations. No new matter is added by these amendments. Therefore, this objection has been overcome and applicants respectfully request its withdrawal.

IV. Nonstatutory double patenting rejection

A. The Office Action states that claims 50-69 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 15-20 and 56-60 of U.S. Patent No. 6,309,633. The Office Action also states that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '633 patent anticipate the instant claims.

A Terminal Disclaimer executed by applicants' attorney is filed herewith, whereby any patent term for the present application extending beyond the term of U.S. Patent No. 6,309,633 is disclaimed. Thus, this rejection has been overcome and applicants respectfully request its withdrawal.

B. The Office Action states that claims 50-63 and 65-68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-67 of copending U.S. application serial no. 09.873,899. The Office Action also states that although the conflicting claims are not identical, they are not patentably distinct from each other. The Office Action further states that the '899 application claims insulin conjugated



to a first polyethylene glycol moiety, which is conjugated through a hydrolyzable bond to a second polyethylene glycol moiety, which is conjugated to a lipophilic moiety. It is further stated in the Office Action that the polyethylene glycol moieties can have at least two polyethylene glycol subunits, the lipophilic moieties can be alkyl or fatty acid moieties and the conjugates are amphiphilically balanced so that each conjugate is aqueously soluble and able to penetrate biological membranes. The Office Action goes on to state that the '899 application does not claim applicants' specific H, H', and fatty acid moiety sizes, but that it would have been obvious to one of ordinary skill in the art to determine all operable and optimal H, H' and fatty acid moiety sizes for the claimed conjugates of the '899 application because the '899 application recites in its claims that PEG size is to be determined, because polymer size is an art-recognized result-effective variable which is routinely determined and optimized in the polymer and conjugate arts and because it is necessary to determine and optimize H, H' and fatty acid moiety sizes in the claimed conjugates of the '899 application in order to amphiphilically balance the conjugates as is required in claim 28 of the '899 application. The Office Action concludes with the statement that this is a provisional rejection because the conflicting claims have not in fact been patented.

As the Examiner points out, this is only a provisional rejection because the claims of the '899 patent have not yet issued. Therefore, applicants request that this rejection be withdrawn and that the claims of the pending application be allowed. Should claims in the '899 application be allowed before the allowance of claims in the present application, applicants will address this issue at that time.

V. Reference 99 of the Information Disclosure Statement filed February 3, 2003

The Office Action states that reference 99 is crossed off of the Information Disclosure Statement and was not considered because it is not in the English language and no concise explanation of its relevance was provided as required under 37 C.F.R. § 1.98(a)(3)(i).



Applicants will submit an English version of reference 99 in a Supplemental Information Disclosure Statement to be filed shortly.

VI. New claims 70-75

New claims 70-75 are added herein as dependent from claim 50, and recite the drug-oligomer conjugate of claim 50, wherein H' and L are present as a component H'-L having the formula of Formula 3, 4, 6, 7, 8 or 9, respectively. Support for these claims is found throughout the specification, and in particular on pages 9-10 and 24-25. No new matter is added by these new claims. As these claims are dependent from claim 50, which is free of the prior art, new claims 70-75 are free of the prior art as well and are allowable as presented herein. Applicants therefore respectfully request their entry and allowance, along with the claims currently pending in this application.

For the foregoing reasons, applicants believe that all of the pending objections and rejections have been adequately addressed and that the claims as presented herein are in condition for allowance. The Examiner is encouraged to contact the undersigned directly if such contact will expedite the examination and allowance of these claims to issue.



Attorney Docket No. 9235-74

Application Serial No.: 10/018,879

Filed: August 5, 2002

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A check in the amount of \$108.00 (for additional claim fees) is enclosed. This amount is believed to be correct. However, the Commissioner is hereby authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



Mary L. Miller
Registration No. 39,303



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Date of Deposit: July 18, 2003

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.


Cathy A. Schetzina